

## Supporting Statement A

### National Park Service Institutional Animal Care and Use Committee (NPS IACUC) Amendment, Annual Review, Exhibition, and General Submission Forms

OMB Control Number 1024--New

**Terms of Clearance:** None. This is a collection currently in use without a valid OMB Control Number.

#### General Instructions

A completed Supporting Statement A must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified below. If an item is not applicable, provide a brief explanation. When the question "Does this ICR contain surveys, censuses, or employ statistical methods?" is checked "Yes," then a Supporting Statement B must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

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#### Justification

**1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.**

Pursuant to the Animal Welfare Act (AWA), its Regulations (AWAR), and the Interagency Research Animal Committee (IRAC), any entity or institution that uses vertebrate animals for research, teaching, or exhibition purposes must have an oversight committee to evaluate all aspects of that institution's animal care and use. To be in compliance, the National Park Service (NPS) is responsible for managing and maintaining an Institutional Animal Care and Use Committee (IACUC) that provides the experience and expertise necessary to assess and approve all research, teaching, and exhibition activities involving vertebrate animals on NPS managed lands and territories.

All research, teaching, and exhibition projects involving the use and care of vertebrate animals taking place on NPS territories must be reviewed and approved by the NPS IACUC prior to starting. Principal Investigators (PI) are required to submit one of the following forms for consideration by the committee:

- The NPS IACUC General Submission (GS) form

- The NPS IACUC Exhibitor Submission (ES) form
- The NPS IACUC Amendment form
- The NPS IACUC Annual Review form

As determined by the AWA, The NPS Institutional Animal Care and Use Committee (NPS IACUC), is a self-regulating entity that currently consists of a Chair and two additional posts (a veterinarian to serve as the “Attending Veterinarian” and another individual to serve as the “Unaffiliated Member At-Large”).

#### Relevant Legislation:

- ***Animal Welfare Act Regulations*** 7 U.S.C. 2131-2159; **§2.31, d, 1**  
“the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing...”
- ***Animal Welfare Act (AWA) of 1966 (PL 89-544)***  
This is the only Federal law in the [United States](#) that regulates the treatment of animals in research and exhibition. Other laws, policies, and guidelines may include additional species coverage or specifications for animal care and use, but all refer to the Animal Welfare Act (otherwise known as the "AWA") as the minimally acceptable standard for animal treatment and care.
- ***NPS Organic Act, 16 U.S.C. §a-1***  
“...which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations”.

**2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection. Be specific. If this collection is a form or a questionnaire, every question needs to be justified.**

The NPS IACUC uses this information to ensure that sufficient and relevant information is available to evaluate proposed research projects or exhibits involving the use of animals within NPS units. Each animal project must be reviewed by the NPS IACUC committee every three years (or more often as determined by the committee). The review process covers the following points:

- Identification of the species and approximate number of animals to be used.
- Rationale for involving animals, and for the appropriateness of the species and numbers used.
- A complete description of the proposed use of the animals.
- A description of procedures designed to assure that pain, stress, and discomfort experienced by animals will be limited to that which is unavoidable in the conduct of scientifically valuable

research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

- Description and support of any euthanasia method to be used.

In review, the IACUC is required to ensure that the proposed work is consistent with the treatment of animals as described in the Animal Welfare Act, and that the following points are covered:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia (PDF), unless a deviation is justified for scientific reasons in writing by the investigator.

The General Submission (GS) and the Exhibitor forms require the following information:

- A project narrative which includes: the title, a statement of the objectives to be addressed, scope of the proposed project, literature review, and description of the methods and procedures to be used.
- A description of the qualifications of the principal investigators, all personnel involved, and delegated attending veterinarians on the project.

- Details and descriptions of animals used in the project.
- A list of the permits necessary to conduct the project.
- A signed declaration of compliance with the procedures and methods outlined in The Animal Welfare Act, its Regulations, and the Interagency Research Animal Committee.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden and specifically how this collection meets GPEA requirements**

Electronic submission is strongly encouraged through the program's website

(<http://www1.nrintra.nps.gov/brmd/wildlifehealth/iacuc/>). Respondents can also print the forms and submit by way of regular mail.

**4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

The information that we collect is not available from any other source. Other than the general identifying information (name, address, telephone number, email address), the information collected is unique for individuals submitting applications for projects or exhibits involving the use of vertebrate animals in NPS units

**5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.**

The collection of this data will not impact small businesses.

**6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden**

If we do not collect this information, the NPS would be in violation of the Animal Welfare Act and its Regulations. Specifically, the NPS would not have the information necessary to comply with their annual requirements to prepare a report for the USDA concerning the use of animals in each of following categories:

- (1) Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

- (2) Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.
- (3) Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.
- (4) Number of animals upon which teaching experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

**7. Explain any special circumstances that would cause an information collection to be conducted in a manner:**

- \* requiring respondents to report information to the agency more often than quarterly;
- \* requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- \* requiring respondents to submit more than an original and two copies of any document;
- \* requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
- \* in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- \* requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- \* that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- \* requiring respondents to submit proprietary trade secrets, or other confidential information, unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

There are no circumstances that require the information to be collected in a manner inconsistent with OMB guidelines.

- 8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice [and in response to the PRA statement associated with the collection over the past three years] and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.**

**Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. [Please list the names, titles, addresses, and phone numbers of persons contacted.]**

**Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years — even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

On September 26, 2012, a 60-day Federal Register notice (77 FR 59222) was published announcing this information collection. Public comments were solicited for 60 days ending November 26, 2012. We received one comment – via e-mail - in response to that notice. The respondent's comment is copied below:

*[TLE TO HE ]TAXPAYERS, WHICH PAYS THE SALARIES AND EXPENSE OF THIS AGENCY, WANTS ALL USE OF ANY ANIMAL DETAILED ON TEH WEBSITE OF THIS AGENCY, WHERE IS EASILY AVAILABLE TO THE CITIZENRY. THIS IS DETAILED IN PRESIDENT OBAMA'S EXECUTIVE ORDER WHICH SAYS SUCH INFORMATION SHOULD BE AVAILABLE TO AMERICAN CITIZENS. ALL INFORMATION ON SUCH ANIMAL ABUSE MUST BE OUTLINED IN FULL DETAIL ON THE WEB. WE WANT INFORMATION ON THE COSTS OF SUCH EXPERIMENTS OF ANIMALS. WHAT HAPPENS TO THE ANIMALS. WHAT YOU PROVED WITH THIS ABUSE OF THEM. WHY DIDNT YOU USE HUMAN SUBJECTS? WHY DIDNT YOU USE HUMAN TISSUE OR CELLS? THIS SECRECY, SNEAKINESS AND OUT OF CONTROL SPENDING FOR ANIMAL ABUSE MUST STOP. THERE IS NO REASON TO USE DOGS, CATS, COWS, PIGS, GOATS, GUINEA PIGS, APES, MONKEYS FOR SUCH ABUSE. IT IS CLEAR THAT THE AMERICAN PUBLIC IS FED UP WITH THIS MISUSE AND OUT OF CONTROL SPENDING FOR THESE PALS GIVEN GRANTS FOR PROJECTS THAT BENEFIT AMERICA IN NO WAY AT ALL. THIS COMMENT IS FOR THE PUBLIC RECORD. PLEASE ADVISE WHERE YOUR SITE IS SO THAT I CAN KEEP UP TO DATE ON THE ANIMALS ABUSED BY THIS AGENCY, THIS COMMENT IS FOR THE PUBILC RECORD. JEAN PUBLIC*

We did not make any changes to this collection based on this comment.

However, in addition to publishing the 60 day Federal Register notice we actively solicited peer reviews from former IACUC participants, to provide feedback about each of the forms. We asked them to provide feedback about the clarity of instruction and the estimated time to complete a prototype of an on-line version of the forms. Based on their previous experiences with the IACUC process, the individuals listed below provided suggestions and feedback concerning the, structure, clarity of the procedure and approximate length of time it would take to complete the forms. The reviewers said that the website's instructions were clear and easy to follow, and that the forms were straightforward and that the instructions were very helpful. We did not change the content of the forms or the website,

because the reviewers suggested that no changes or updates were necessary at this time. The respondents concurred with our estimated burden time needed would be 3 hours to complete the General Submission or Exhibitor forms; 15 minutes to complete the Amendment form; and 10 minutes to complete the Annual Review form. These estimates reflect the time it will take each applicant to prepare the narrative and provide the additional background information needed to complete the application.

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**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

We do not provide payment or gifts to respondents in this collection.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.**

We do not provide any assurance of confidentiality; however, the information that we collect is subject to the requirements of the Freedom of Information Act.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

The collection does not include questions of a sensitive nature.

**12. Provide estimates of the hour burden of the collection of information. The statement should:**

- \* Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- \* If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- \* Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here.**

Based on our administrative experiences plus the outreach described in item 8, we expect to receive 190 annual responses from a combination of federal, state and local agencies as well as from individuals representing the private sector. We estimate that it will take an average of 3 hours to complete the General or Exhibitor Submission forms; 15 minutes to complete the Amendment form; and 10 minutes to complete the Annual Review form, totaling 348 burden hours.

Variations can be expected in the reporting burden for completion of the forms in this collection because of the differences in user familiarity and the amount of information provided in each form and the time it takes for individual computer systems to make the connection with our website. The data entry level sought is the same as used in most computer operating program (no advanced knowledge, training, or expertise is required). For the respondents reporting more than one species per report the additional time has been considered in the average time it takes to complete the form.



**Table 1. Estimated Annual Burden Hours**

<b>Respondent and forms</b>	<b>Responses</b>	<b>Completion Time Per form</b>	<b>Burden Hours</b>
State and Local Agencies	65		195
General Submission Form	15	3 Hours	45
Exhibitor Submission Form	30	3 Hours	8
Amendment Form	30	15 Minutes	5
Annual Review Form		10 Minutes	
<b>SUBTOTAL</b>	<b>140</b>		<b>253</b>
Private (non-profit)	25		75
General Submission Form	5	3 Hours	15
Exhibitor Submission Form	10	3 Hours	3
Amendment Form	10	15 Minutes	2
Annual Review Form		10 Minutes	
<b>SUBTOTAL</b>	<b>50</b>		<b>95</b>
<b>TOTAL</b>	<b>190</b>		<b>348</b>

We estimate the dollar value of the annual burden hours to be \$16,002 (Table 2). The estimated dollar value of the burden hours for this collection takes into account the nature of our respondents state and local government agencies and Private businesses, (this includes university and non-profit employees). This estimated dollar value included the multiplier for benefits and is based on the National Compensation Survey: Occupational Wages in the United States published by the Bureau of Labor Statistics Occupation and Wages, (BLS news release USDL-12-1830 for Employer Costs for Employee Compensation— June 2012 at <http://www.bls.gov/news.release/ecec.nr0.htm>, September 11, 2012). The particular values utilized are:

States and Local Agencies: Average hourly wage is \$29.75 multiplied by 1.5 to account for benefits (\$44.63). To obtain the rate for State and local government, we used data from [http://www.bls.gov/oes/current/oes\\_nat.htm#19-0000](http://www.bls.gov/oes/current/oes_nat.htm#19-0000) (Table 19-1011- Zoologist and Wildlife Biologists mean hourly wage).

Private Businesses: Average hourly wage is \$35.42 multiplied by 1.4 to account for benefits (\$49.59). To obtain the rate for professionals in the private sector we used data from <http://www.bls.gov/news.release/pdf/ocwage.pdf> Table 1.

**Table 2.** Estimated Dollar Value of Annual Burden Hours

Sector	Total Annual Number of Responses	Total Annual Burden Hours	Dollar Value of Burden Hours (Including Benefits)	Total Dollar Value of Annual Burden Hours
State and Local Agencies	140	253	\$44.63	\$11,291
Private Businesses (non-profit and Private Universities)	50	95	\$49.59	\$4,711
TOTAL	190	348		\$16,002

**13. Provide an estimate of the total annual non-hour cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected in item 12.)**

- \* The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information (including filing fees paid for form processing). Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.
- \* If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- \* Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There is no non-hour cost burden to applicants resulting from this collection. There are no fees associated with this process or requirements.

**14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.**

The total annual cost to the Federal Government is \$196,563. This includes the cost to the Federal Government for salaries and benefits for administering this information collection \$194,063 and operational expenses \$2,500. Table 3 below shows Federal staff and grade levels associated with this information collection. We used the Office of Personnel Management Salary Table 2012-DEN ([http://www.opm.gov/flsa/oca/12tables/html/den\\_h.asp](http://www.opm.gov/flsa/oca/12tables/html/den_h.asp)) to determine the hourly rate. We multiplied the hourly rate by 1.5 to account for benefits (as implied by the BLS news release 10-10-0774 mentioned above). Operational expenses are listed in Table 4 below.

**Table 3. Annual Cost to the Federal Government**

Position	Grade/ Step	Hourly Rate	Hourly Rate incl. benefits (1.5 x hourly pay rate)	Estimated time (hours)	Cost per federal staff (Hourly Pay Rate incl. Benefits)
IACUC Administrator	GS 7/5	\$22.61	\$33.92	1,664	\$56,443
NPS Veterinarian	GS 12/4	\$38.92	\$58.38	1,664	\$97,144
IACUC Committee Member	GS 12/4	\$38.92	\$58.38	520	\$20,238
IACUC Committee Member	GS 12/4	\$38.92	\$58.38	520	\$20,238
<b>Total</b>					\$194,063

**Table 4. Operational Expenses**

Operational Expenses	Estimated Cost
Contract Support website oversight, database management, and maintenance	\$2,500

**15. Explain the reasons for any program changes or adjustments.**

This collection is currently being conducted without a valid OMB Control Number or expiration date.

**16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time**

**schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.**

The information collected will not be tabulated or published for statistical use. The forms will be stored in a database to maintain documentation of approved proposals.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

We will display the OMB control number and expiration date on all information collection instruments and the website.

**18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."**

There are no exceptions to the certification statement.